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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,714	09/21/2006	Elisabeth Meyer	930008-2207	5929

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EXAMINER	
CHEN, CATHERYNE	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
10/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/569,714	MEYER ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *7,9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8, 11-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendments filed on July 24, 2008 has been received and entered.

Currently, Claims 1-25 are pending. Claims 1-6, 8, 11-25 are examined on the merits.

Election/Restrictions

Claims 7, 9-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on Nov. 16, 2007.

Applicant's election with traverse of the species matrix type patch, synthetic rubber, styrene-butadiene-styrene-block-copolymer, polybutylacrylate, N-methyl-pyrrolidone, organic acids, polyester in the reply filed on Nov. 16, 2007 is acknowledged.

Response to Arguments

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (US 6455066 B1) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Fischer et al. teaches a patch comprising a pressure sensitive adhesive comprising pharmaceutically acceptable salt and soybean oil (Claim 1), with aloe vera (Claim 2), backing is polyolefin, polyester, (Claim 4), polyolefin foil (Claim 5), with thickness of from about 0.6 mm to about 1.0 mm (Claim 6). Local anesthetic can be acetylsalicylic acid as an organic acid, buprenorphine and pharmaceutically acceptable salts thereof (column 5, lines 41-42, 44-46, 60-61). Penetration agents of N-methyl pyrrolidone (column 7, lines 9, 14). Preferred patches include matrix type patch (column 8, line 7). Preferably the adhesive is a synthetic rubber (column 8, lines 63-64). The adhesive may contain a crosslinker (column 9, lines 3-6).

The reference does teach that each of the claimed ingredients is suitable for combination in a pharmaceutical composition. Thus, an artisan of ordinary skill would be reasonably expected that the claimed ingredient could be combined together to produce a single pharmaceutical product. This reasonable expectation of success would motivate the artisan to combine the claimed ingredients together into a single composition.

Applicant argues that Fischer et al. is directed to an intradermal composition, but not a transdermal formulation.

In response to Applicant's claim that the formulation is intradermal, Fischer et al. teaches formulation that is applied topically to the skin as a patch, then the chemicals are intradermally delivered (Claim 1). The Applicant's claim uses the same delivery system; therefore, for the drugs to be delivery from the skin to the inside of the skin, then the drugs would have to be transdermally delivered, then intradermally delivered. Thus, the reference teaches the claims.

Applicant argues that opioid analgesic and the penetration activity of aloe vera are not taught by Fischer et al.

In response to Applicant's argument that opioid analgesic is not taught by Fischer et al., as long as the claimed ingredients are taught by Fischer et al. then the opioid analgesic is taught. As to the penetration activity of aloe vera, the fact that Fischer et al. uses aloe vera gel as a patch demonstrates that aloe vera is a known ingredient for patch. The mechanism of aloe vera does not have to be disclosed.

Applicant argues that Fischer et al. does not teach matrix-type patch, synthetic rubber, styrene-butadiene-styrene block copolymer.

In response to Applicant's argument that Fischer et al. does not teach matrix-type patch or synthetic rubber, the reference teaches patches include matrix type patch (column 8, line 7). Preferably the adhesive is a synthetic rubber (column 8, lines 63-64). Thus, the claimed ingredients are taught. As to styrene-butadiene-styrene block copolymer, that ingredient is in Claim 8. Thus, it is not part of this rejection.

Claims 1-6, 8, 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (US 6455066 B1) as applied to claims 1-6, 11-25 above, and further in view of Nielsen (US 6171594 B1) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Fischer et al. teaches a patch for skin comprising a pressure sensitive adhesive comprising pharmaceutically acceptable salt and soybean oil (Claim 1), with aloe vera (Claim 2), backing is polyolefin, polyester, (Claim 4), polyolefin foil (Claim 5), with thickness of from about 0.6 mm to about 1.0 mm (Claim 6). Local anesthetic can be acetylsalicylic acid as an organic acid, buprenorphine and pharmaceutically acceptable salts thereof (column 5, lines 41-42, 44-46, 60-61). Penetration agents of N-methyl pyrrolidone (column 7, lines 9, 14). Preferred patches include matrix type patch (column 8, line 7). Preferably the adhesive is a synthetic rubber (column 8, lines 63-64). The adhesive may contain a crosslinker (column 9, lines 3-6). However, it does not teach styrene-butadiene-styrene block copolymer.

Nielsen teaches adhesive agent for human or animal skin with styrene-butadiene-styrene copolymer (column 5, lines 37-38).

The references also do not specifically teach combining styrene-butadiene-styrene copolymer and rubber adhesives together. The reference does teach that these are adhesives used for skin (see discussion above). As discussed in MPEP 2144.06:

> It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be

used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, is would be obvious to combine styrene-butadiene-styrene copolymer with other skin adhesives because they are taught in the reference to have the same purpose.

Applicant argues that there is no reason to combine the references because the references do not use the ingredients for transdermal administration.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Nielsen teaches skin adhesive agents (column 1, lines 18) and Fischer et al. teaches topical application of intradermal penetrating agents (abstract). Both references use the composition for skin application.

Applicant argues that Fischer et al. is directed to an intradermal composition, but not a transdermal formulation.

In response to Applicant's claim that the formulation is intradermal, Fischer et al. teaches formulation that is applied topically to the skin as a patch, then the chemicals are intradermally delivered (Claim 1). The Applicant's claim uses the same delivery

system; therefore, for the drugs to be delivery from the skin to the inside of the skin, then the drugs would have to be transdermally delivered, then intradermally delivered. Thus, the reference teaches the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/

Primary Examiner, Art Unit 1655